

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 18 Jun 2026

Print date: 19 Jun 2026

Version: 1.1



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HISTOLITH NaOCl 5%

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name/designation:

HISTOLITH NaOCl 5%

Other means of identification:

Article No. : 0032120 (200 ml), 0032112 (500 ml)

Additional information:

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH). As a medicinal product this article is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according to this regulation.

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture:

Medicinal product for dental application. Observe instructions for use.
for professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

lege artis Pharma GmbH + Co. KG

Breitwasenring 1

72135 Dettenhausen

GERMANY

Telephone: +49 (0) 71 57 / 56 45 - 0

Telefax: +49 (0) 71 57 / 56 45 - 50

E-mail: info@legeartis.de

Website: www.legeartis.de

E-mail (competent person): sicherheitsdatenblaetter@legeartis.de

1.4 Emergency phone number

24h: +49 (0) 551 / 192 40, +49 (0) 71 57 / 56 45 - 0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Serious eye damage/eye irritation (<i>Eye Dam. 1</i>)	H318: Causes serious eye damage.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Acute 1</i>)	H400: Very toxic to aquatic life.	Calculation
Corrosive to metals (<i>Met. Corr. 1</i>)	H290: May be corrosive to metals.	Test data
Skin corrosion/irritation (<i>Skin Corr. 1A</i>)	H314: Causes severe skin burns and eye damage.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	Calculation

Additional information:

Contains: Sodium hypochlorite solution

Contact with acids liberates very toxic gas.

Warning! Do not use together with other products. May release dangerous gases (chlorine).

Precautionary statements:

Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection. IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get immediate medical advice/attention.

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2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Additional information:

As a medicinal product this article is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according to this regulation.

2.3 Other hazards

No data available.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description:

Sodium hypochlorite (NaOCl) in aqueous solution, alkaline

Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
CAS No.: 7681-52-9 EC No.: 231-668-3 REACH No.: 01-2119488154-34	Sodium hypochlorite (active chlorine) Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Eye Dam. 1 (H318), Met. Corr. 1 (H290), Skin Corr. 1B (H314)  Danger EUH031 M-factor (acute): 10 M-factor (chronic): 1 Additional information: Specific concentration limit (SCL): EUH031 ≥ 5 %	≥ 5 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off immediately all contaminated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

No special measures are necessary.

In case of inhaling spray mist, consult a physician. Provide fresh air.

In case of skin contact:

Wash with plenty of water. In case of skin irritation, consult a physician.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Get immediate medical advice/attention.

Following ingestion:

Rinse mouth thoroughly with water. Let water be drunk in little sips (dilution effect). Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Product does not burn. Use extinguishing measures to suit surroundings.

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5.2 Special hazards arising from the substance or mixture

No special fire protection measures are necessary.

Hazardous combustion products:

In case of fire may be liberated: hydrogen chloride (HCl), Chlorine (Cl₂), sodium hydroxide.

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Personal precautions:

Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes and skin. Special danger of slipping by leaking/spilling product. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2 For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For containment:

Wipe up with absorbent material (eg. cloth, fleece). Handling larger quantities: Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

For cleaning up:

Water (with cleaning agent)

6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures

Advices on safe handling:

Avoid contact with eyes and skin. Take off immediately all contaminated clothing. Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Environmental precautions:

Discharge into the environment must be avoided.

Advices on general occupational hygiene

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Wash contaminated clothing before reuse. Apply skin care products after work.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Conditions to avoid: Heat, Light, UV-radiation/sunlight, Temperature > 10 °C (slow decomposition).

Recommended storage temperature: 2 - 8 °C

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Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Do not store together with: Acids.
Keep/Store only in original container.

Hints on storage assembly:

Do not store together with: Acids, Reducing agent
Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

Recommendation:

Medicinal product for dental application.
Observe instructions for use.

SECTION 8: Exposure controls / Personal protection

8.1 Control Parameters

No data available.

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

8.2.2 Personal protection equipment



Eye/face protection:

Eye glasses with side protection (EN 166).

Skin protection:

Tested protective gloves must be worn (EN ISO 374).

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material: $\geq 0,11$ mm

Breakthrough time: ≥ 480 min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The exact breakthrough time must be requested from the protective glove manufacturer and must be observed. Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Usually no personal respiratory protection necessary. Provide adequate ventilation.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Other protection measures:

Wear suitable protective clothing.

8.2.3 Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: liquid

Form: liquid

Colour: light yellow-green

Odour: like Chlorine

Flammability: No

Safety relevant basic data

Parameter	Value	at	① Method ② Remark
pH	12.2	20 °C	
Melting point	No data available.		

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Parameter	Value	at	① Method ② Remark
Freezing point	No data available.		
Initial boiling point and boiling range	> 100 °C		
Flash point	Not applicable.		
Evaporation rate	No data available.		
Auto-ignition temperature	Not applicable.		
Upper/lower Flammability or explosive limits	Not applicable.		
Vapour pressure	No data available.		
Vapour density	No data available.		
Density	1.1 g/mL	20 °C	
Bulk density	Not applicable.		
Water solubility	completely miscible		
Dynamic viscosity	No data available.		
Kinematic viscosity	No data available.		

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

See section 10.3

10.2 Chemical stability

Slow decomposition: > 10 °C

10.3 Possibility of hazardous reactions

The product is chemically stable under recommended conditions of storage, use and temperature.
Reaction / Violent reaction with: Acids. Formation of: Chlorine (Cl₂)! Reaction with: Reducing agent, metals (including their alloys)

10.4 Conditions to avoid

Light, UV-radiation/sunlight, Temperature > 10 °C (slow decomposition).
Impurities may cause catalytic decomposition.

10.5 Incompatible materials

Acids; Reducing agent; Metals (including their alloys): Cu, Ni, Co. Fabrics, textiles and apparel.

10.6 Hazardous decomposition products

In case of fire may be liberated: hydrogen chloride (HCl), Chlorine (Cl₂), sodium hydroxide.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

Causes severe burns.

Serious eye damage/irritation:

Causes serious eye damage.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

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Germ cell mutagenicity:

Based on available data, the classification criteria are not met.

Carcinogenicity:

Based on available data, the classification criteria are not met.

Reproductive toxicity:

Based on available data, the classification criteria are not met.

STOT-single exposure:

aerosol or mist formation: May cause respiratory irritation.

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

Based on available data, the classification criteria are not met.

Aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

SECTION 12: Ecological information

12.1 Toxicity

Sodium hypochlorite (active chlorine) CAS No.: 7681-52-9 EC No.: 231-668-3

LC₅₀: 0.01 - 0.1 mg/L 4 d (fish)
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EC₅₀: 0.01 - 0.1 mg/L 2 d (crustaceans, Daphnia magna (Big water flea))

Aquatic toxicity:

Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Accumulation / Evaluation:

No indication of bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Sodium hypochlorite (active chlorine) CAS No.: 7681-52-9 EC No.: 231-668-3

Results of PBT and vPvB assessment: —
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The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Completely emptied packages can be recycled.

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Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Do not allow to enter into surface water or drains. Collect in closed and suitable containers for disposal. Waste for disposal is to be classified and labelled.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI-/IATA-DGR)
14.1 UN number or ID number			
UN 1791	UN 1791	UN 1791	UN 1791
14.2 UN proper shipping name			
HYPOCHLORITE SOLUTION	HYPOCHLORITE SOLUTION	HYPOCHLORITE SOLUTION	HYPOCHLORITE SOLUTION
14.3 Transport hazard class(es)			
			
14.4 Packing group			
II	II	II	II
14.5 Environmental hazards			
		 MARINE POLLUTANT	
14.6 Special precautions for user			
No data available.	No data available.	No data available.	No data available.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

14.8. Additional information

Small amounts: Transport as "Limited Quantity" according to chapter 3.4 ADR/RID / Transport as "Excepted Quantity" according to chapter 3.5 ADR/RID.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU legislation

Authorisations:

Contains no substances listed in REACH Annex XIV.

Restrictions on use:

Contains no substances subject to the restrictions of Annex XVII of the REACH Regulation.

Other regulations (EU):

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Directive 93/42/EEC concerning medical devices. Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

15.1.2 National regulations

No data available.

15.2 Chemical Safety Assessment

No data available.

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SECTION 16: Other information

16.1 Indication of changes

Changes executed in version 1.1:

General revision of all sections

16.2 Abbreviations and acronyms

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

ATE = acute toxicity estimate

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging

DMEL = Derived Minimum Effect Level

DNEL = Derived No Effect Level

EC₅₀ = Median effective concentration

ECB = European Chemicals Bureau

EEC = European Economic Community

EINECS = European Inventory of Existing Commercial Chemical Substances

ELINCS = European List of Notified Chemical Substances

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC₅₀ = Inhibition concentration, 50%

IMDG = International Maritime Code for Dangerous Goods

IUCLID = International Uniform Chemical Information Database

LC₅₀ = Lethal concentration, 50%

LD₅₀ = Median lethal dose

LC0 = lethal concentration, 0%

LOAEL = lowest-observed-adverse-effect level

MARPOL = International Convention for the Prevention of Marine Pollution from Ships

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Content

PBT = Persistent, Bioaccumulative and Toxic substance

PNEC = Predicted No-Effect Content

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

STP = Sewage Treatment Plant

TLV®/TWA = Threshold limit value - time-weighted average

TLV®STEL = Threshold limit value - short-time exposure limit

VOC = Volatile Organic Compounds

vPvB = very Persistent and very Bioaccumulative

16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <https://www.echa.europa.eu>

ECHA, C&L Inventory: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>

ECHA, Registered substances: <https://echa.europa.eu/information-on-chemicals/registered-substances>

GESTIS, Information system on hazardous substances: <https://www.gestis.dguv.de/search>

GESTIS, International Limit Values: <https://limitvalue.ifa.dguv.de>

Hörath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz

Safety data sheets of the manufacturers

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16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Serious eye damage/eye irritation (<i>Eye Dam. 1</i>)	H318: Causes serious eye damage.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Acute 1</i>)	H400: Very toxic to aquatic life.	Calculation
Corrosive to metals (<i>Met. Corr. 1</i>)	H290: May be corrosive to metals.	Test data
Skin corrosion/irritation (<i>Skin Corr. 1A</i>)	H314: Causes severe skin burns and eye damage.	Calculation
Hazardous to the aquatic environment (<i>Aquatic Chronic 2</i>)	H411: Toxic to aquatic life with long lasting effects.	Calculation

16.5 List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental hazard information	
EUH031	Contact with acids liberates toxic gas.

16.6 Training advice

No data available.

16.7 Additional information

The information in this safety data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.